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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,475	08/20/2001	Olav K. Lyngberg	110.00810101	7111

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EXAMINER

CHEU, CHANGHWA J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/16/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/647,475

Applicant(s)

LYNGBERG ET AL.

Examiner

Jacob Cheu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-99 is/are pending in the application.
- 4a) Of the above claim(s) 23-47 and 49-99 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-24 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election on Group I, claims 1-24, 48 with traverse on Paper No. 15 has been received and acknowledged. Applicant's arguments have been considered but are not persuasive. Because the base claim (claim 1) is not novel and can be read on prior art, such as Ishizaki (USP 5026641) (See below), therefore Group I- VII do not meet the requirement of unity of invention. The requirement is still deemed proper and therefore is made **FINAL**.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 9, 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 9, "the recombinant cell is optimized for desiccation tolerance" is vague and indefinite. It is unclear how one skilled in the art to "optimize" cell for this purported purpose.

With respect to claim 15, "wherein the biostructure is non-hydrated" is vague and indefinite. Since the device comprising at least one metabolically active biological material, i.e. cells, it is inherently essential to maintain the metabolically active of the cells in a "hydrated" state. Applicant needs to clarify.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 6, 7, 8, 10 are rejected under 35 U.S.C. 102 (b) as being anticipated by Ishizaki (USP 5026641).

Ishizaki teaches culturing bacterial in device, i.e. cell culture dish, comprising metabolically active bacteria with a serum treated with natural rubber latex to accelerate cell growth for aerobic and anaerobic condition. (See Abstract; Col. 2, line 21-30) Ishizaki teaches using the culturing medium containing metal and salts, i.e. K, Mg, Cu, Fe, and various essential nutrients necessary for cell growth. (Col. 4, Examples 1 and 2)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1, 6, 7, 8, 10 are rejected under 35 U.S.C. 102 (a) as being known to the public.

It is known that commercially available condom which can be viewed as a biological device comprising a nonporous latex membrane. In order to test the efficacy of the spermicides or the effectiveness of non-leakingness, tested cells are placed in this biological device to measure the effectiveness and/or the leakiness of the condom. Therefore, the instant recited biological device is not novel and was known to the public.

6. Claims 1-3, 6- 20, 23-24 and 48 are rejected under 35 U.S.C. 102 (a) as anticipated by Lyngberg et al. (J. Ind. Microbiol. Biotech. (1999) 23: 668-676)

Lyngberg et al. teach using a microbial biosensor to detect environmental contaminant, i.e Hg (II). (Abstract) Lyngberg et al. teach immobilizing E Coli unto cell patch comprising

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with nonporous/porous latex layers with polymer polyester substrate, and dried the coated layers at 4 C, i.e. non-hydration. (See page 669-670, Latex cell immobilization section; Figure 2) Lyngberg et al. also teach incorporate photon emission detector to measure the luciferase activity which is an indicator of the presence of the environmental Hg (II) analyte. The thickness of the entire device and the biostructure of Lyngberg et al. do not exceed 500 micron. (See Figure 2)

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 4, 5 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Lyngberg et al.

Lyngberg et al. reference has been discussed but is silent in specifically teaching that the biostructure comprises no greater than about 75% or 50% by volume biological material.

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate these volume range features, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

7. Claims 21-22 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Lyngberg et al. in view of Anderson et al. (USP 2001/0041339)

Lyngberg et al. reference has been discussed but does not specifically teach using an electronic device, i.e. electrode for the recited biological structure. Anderson et al. teach a microarray comprising bundle of fibers to increase diffusion the ligand through the microarray by electrodes located on both sides of the microarray in order to enhance the spectrophotometric detection. (Section 108, Col. 8) Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided Lyngberg et al. with the electrodes as taught by Anderson et al. for attraction more analyte, i.e. Hg(II), for a better detection.

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

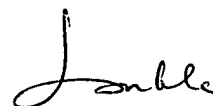
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.

Jacob Cheu
Examiner
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June 5, 2003



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

05/13/03